K112414

510(k) Summary of Safety and Effectiveness

JUN 2 2 2012

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number:

Date of Summary Preparation: May 29, 2012

Manufacturer:

Phadia AB
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510 (k) Contact Person:

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Device Name: EliA™ ß2-Glycoprotein I IgA Immunoassay

Common Name: β2-Glycoprotein I autoantibody immunological test system

Classification

Product Name	Product Code	Class	CFR
EliA β2-Glycoprotein I IgA	MSV	II	866.5660

Substantial Equivalence to

Varelisa ß2-Glycoprotein I IgA Antibodies K040450

Intended Use Statement of the New Device

EliA ß2-Glycoprotein I IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to ß2-Glycoprotein I in human serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA ß2-Glycoprotein I IgA uses the EliA IgA method on the instruments Phadia 100 and Phadia 250.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

Phadia® 100/Phadia® 250 are fully automated immunoassay analyzers, which include software for evaluation of test results.

General Description of the New Device

The new device belongs to a fully integrated and automated system for immunodiagnostic testing. It comprises a Fluorescence-Immunoassay test system using EliA single wells as the solid phase and is intended to be performed on the instruments Phadia 100 and Phadia 250.

The conjugate for the EliA IgA method is mouse anti-human IgA beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate.

The total IgA calibration is based on a set of six WHO-standardized IgA Calibrators derived from human serum. They are used to establish an initial calibration curve, which may be used for up to 28 days on additional assays and can be stored by the instrument. Each additional assay includes calibrator (curve) controls that have to recover in defined ranges to ensure that the stored calibration curve is still valid. The Fluorescence-Immunoassay test system includes test-specific, method-specific and general reagents that are packaged as separate units.

Test Principle of the New Device

The EliA Wells are coated with the following antigen:

Test	**Antigen coated to the wells:**
EliA ß2-Glycoprotein I IgA Well	Human β2-Glycoprotein I antigen

If present in the patient's specimen, antibodies to the antigen mentioned above bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgA antibodies (EliA IgA Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The higher the response value, the higher the amount of antibody bound and detected in the sample tested. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

Device Comparison

The new and the predicate device both represent non-competitive solid phase ELISAs. Both IVDs are used as an aid in the diagnosis of antiphospholipid syndrome (APS) and to evaluate the thrombotic risk in patients with systemic lupus erythematosus (SLE).

Laboratory equivalence

The comparability of predicate device and new device is supported by a data set including

- **results obtained within a comparison study between new and predicate device**
- **results obtained for clinically defined sera**
- **results obtained for samples from apparently healthy subjects (normal population).**

In summary, all available data support that the new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Phadia AB
c/o Martin Mann
Regulatory Affairs Manager
4169 Commercial Avenue
Portage, MI 49002, USA

JUN 2 2 2012

Re: k112414
Trade/Device Name: EliA™ ß2-Glycoprotein I IgA Immunoassay
Regulation Number: 21 CFR §866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MSV
Dated: June 20, 2012
Received: June 21, 2012

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Reena Philip

For Maria M. Chan, Ph.D.
Director
Division Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k112414

Device Name: **EliA™ ß2-Glycoprotein I IgA**

Indications For Use:

EliA ß2-Glycoprotein I IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to ß2-Glycoprotein I in human serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA ß2-Glycoprotein I IgA uses the EliA IgA method on the instruments Phadia 100 and Phadia 250.

Prescription Use __√____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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